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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/438,365 11/12/99 CHU

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STERNE KESSLER GOLDSTEIN & FOX PLLC  
ATTORNEYS AT LAW  
SUITE 600  
1100 NEW YORK AVENUE NW  
WASHINGTON DC 20005-3934

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EXAMINER

EPPS, T	ART UNIT	PAPER NUMBER
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1635

DATE MAILED:

03/28/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/438,365	CHU ET AL.	
	Examiner Janet L Epps	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 12 November 1999.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-109 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 10-28, 30-41, and 43-92 is/are rejected.
- 7) Claim(s) 1-9, 29, 42 and 93-109 is/are objected to.
- 8) Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 18) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other: \_\_\_\_\_.

## DETAILED ACTION

### *Drawings*

1. The drawings filed 11-12-1999 have been approved by the Draftsperson.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1 and 93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the term "wherein" twice, it is likely that applicants intended that this term appear only once in this claim.

Claim 93 provides a definition for terms j k, l, and l. However, it is unclear what these terms refer to since there are no structures corresponding to these terms in the recited compound.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 1-9, 93, 95-105, 107-109 rejected under 35 U.S.C. 102(a) as being anticipated by Wolff et al. (WO 98/29541).

Claims 1-9, 93, 95-105, 107-109 read on a genus of polycationic compounds comprising a structure according to the formula recited in claim 93, wherein there are two Q groups, which can be O, N, or S and may be substituted up to 4 times, additionally the two Q groups are covalently linked together with a biradical organic radical (L). Wherein (L) may comprise (*inter alia*) an alkyl group, ether, amine, urea, thiourea, a phosphate, etc. Additionally, Q may be substituted up to 4 times with an alkyl, alkenyl, an aryl, an alkyl, an alkyl ether, an alcohol, an aminoalcohol, etc. according to the definitions of R1-R6 recited in claim 93, or CH<sub>2</sub>O, CH<sub>2</sub>S, CH<sub>2</sub>NH<sub>2</sub>, C(O), C(NH), C(S), and (CH<sub>2</sub>)<sub>t</sub> (t= 0-100) according to the definition of A1 and A2 recited in this claim. The dependent compound claims are all species of the genus of compounds recited in claim 93. Additionally, the instant claims read on kits comprising the compounds of this invention, compositions comprising said compounds, lipid-aggregates, a method for introducing a polyanion or a biologically active substance into a cell comprising forming a liposome from the compounds of the instant invention and incubating said liposomes with cells, and a method for introducing a biologically active substance into a cell.

Wolff et al. disclose compounds according the formula recited in claim 93 wherein Q is N, R1-R6 are selected from alkyl groups, polyethyleneglycol chains,

polysaccharides and alkyl-amines; A1 and A2 are selected from (CH<sub>2</sub>)<sub>t</sub>, C(NH) or CH<sub>2</sub>NH, and L is an alkyl moiety (see compounds on pages 64-65 of Wolff et al.).

Wolff et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

5. Claims 1-2, 5-6, 93, 95-98 are rejected under 35 U.S.C. 102(e) as being anticipated by Budowsky et al. (US 6,093,564)

Budowsky et al. (Budowsky) disclose compositions according to formula I of the instant application, wherein X= N, and R1, R2, are hydrogen or a hydrocarbon moiety; L is a divalent hydrocarbon containing between 3 and 4 carbon atoms, inclusive (see the compounds in col. 4-5). Budowsky discloses a method of modifying nucleic acids comprising contacting a biological sample containing nucleic acids with a composition encompassed by formula I of the instant application (col. 2-3). In one particular example of the Budowsky invention, the compounds are in a solution of about 0.0001 M to about .015 M having an ionic strength of about .01 M to about 0.5M at a pH of about 6.5-7.5 at a temperature of about 4°C to about 45°C. Budowsky also teaches that the pH of the solution can be adjusted by using buffers used in the art to handle biopolymers or cells, such as acetate, HEPES, MOPS (col. 10).

Budowsky et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

6. Claims 1-2, 5-6, 9, 29, 42, 93-98, 101-109 are red under 35 U.S.C. 102(e) as being anticipated by Haces et al. (US Patent 5,834,439).

Haces et al. disclose highly packed polycationic ammonium, sulfonium and phosphonium lipid compounds according to the general formula I (see col. 3, lines 50-60). The compounds of Haces et al. are encompassed by those of the instant application R1-R6 and A1-A2 (according to the formula recited in claim 93) are selected from alkyl groups, hydroxyalkyl groups, straight or branched alkyl groups unsubstituted or substituted with one or two OH, SH, NH<sub>2</sub> or amine groups, or an aromatic, alicyclic, heterocyclic or polycyclic ring moiety which may be substituted with OH, SH, NH<sub>2</sub>, CH<sub>3</sub>, COCH<sub>3</sub>, or carbonyl groups.

Haces et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

7. Claims 1-2, 5-6, 9, 29, 42, 93, 95-98, 101-109 are rejected under 35 U.S.C. 102(a) as being anticipated by Haces et al. (WO 97/42819A1)

Haces et al. (See formula [I] in all cited Patents) disclose genus of compounds that encompasses compounds according to formula I of the instant application (see formula I on page 4 of the Haces et al. references). The compounds of Haces et al., anticipate those compounds of the instant invention (using terms set forth in the formula found in claim 93), wherein R<sub>3</sub> and R<sub>6</sub> are alkyl groups, R<sub>1</sub> and R<sub>4</sub> are alkyl, or an ester, R<sub>2</sub> and R<sub>5</sub> are hydrogen, C<sub>1</sub>-C<sub>18</sub> linear alkyl, cyanoethyl, aminopropyl, aminobutyl, C<sub>2</sub>-C<sub>4</sub> alkyl guanidinium or amidinium, C or N substituted spermine. Additionally, the compounds of Haces et al. comprises those wherein R<sub>3</sub> and R<sub>6</sub> are not present, specifically when i=0 of the (R<sub>3</sub>)<sub>i</sub> in the compounds according to formula (I) of Haces et al. Furthermore, Haces et al. discloses compositions (including those

comprising DOPE, see page 18) useful for formation of stable complexes with nucleic acids, methods for contacting nucleic acids with said compounds, and methods for delivering said complexes into cells.

Haces et al. teach each and every aspect of the instant application, thereby anticipating Applicant's claimed invention.

8. Claims 1-2, 5-6, 93, 95-98 are rejected under 35 U.S.C. 102(b) as being anticipated by Haces et al..

Henkel discloses polycationic compounds according to the instant invention wherein (referring to the nomenclature in claim 93) Q is N, A1 and A2 are  $(CH_2)_t$  and R1-R6 are alkyl moieties that may be saturated or unsaturated (paragraph bridging pages 1-2).

Henkel teaches each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

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9. Claims 10-28, 30-41, and 43-92 are free of the prior art of record.

10. The following is a statement of reasons for the indication of allowable subject matter: Henkel, Wolff et al., Budowsky et al. Haces et al. (both WO and US patents) cited above do not disclose the precise compounds claimed by Applicants, nor does the art teach a means to synthesize the precise compounds claimed by Applicants. Specifically, neither reference clearly discloses compounds according to claim 93 wherein the quaternized Q group is O or S, all cited references teach wherein Q is N. Additionally, neither reference provides any suggestion or motivation for modifying their disclosed compounds by substituting Q for O or S. Moreover, although the prior art of record discloses polyamide compounds that are species of the broad genus of compounds recited in claim 93, the compounds of claims 10-28, 30-41, and 43-92 represent novel compounds that are neither anticipated nor obvious over the compounds in the cited references.

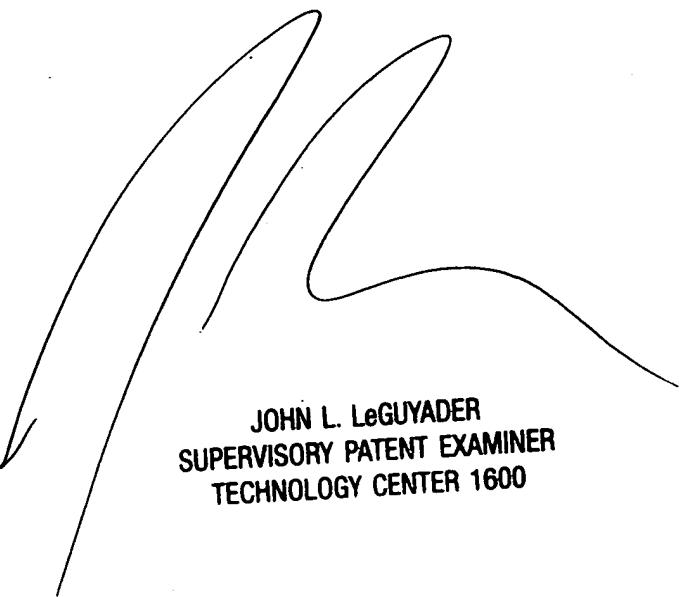
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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps whose telephone number is 703-308-8883. The examiner can normally be reached on Mondays through Friday, 9:00AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

jle  
March 27, 2001



JOHN L. LeGUYADER  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600